REMARKS

Claims 1-20 are in this application and are presented for consideration. By this amendment, Applicant has made changes to the original claims. New claims 19 and 20 have been added.

Claims 1-11, 13-14 and 18 have been rejected as being indefinite. Applicant has now revised these claims paying close attention to the Examiner's comments. Applicant wishes to thank the Examiner for the careful reading of the claims and for the helpful comments. It is believed that all claims as now presented are clear and definite and fully conform with the requirements of the statue.

Claims 1-9, 11, 12-16 and 18 have been rejected as being anticipated by Shapland et al. The rejection is based on the position that Shapland discloses each of the features as claimed.

Shapland discloses a device and a method for invasive treatment. Iontophoresis is applied according to the teachings of Shapland via a catheter which is introduced e.g. in a vessel. The catheter is provided with an electrode embedded within it and a balloon surrounding the electrode. The balloon is filled with a drug containing substance. Shapland et al. does not disclose a device for a transdermal administration of an active compound.

The device and the method according to the invention are for transdermal administration i.e. for a non-invasive administration. The invention and the teachings of Shapland et al. represent very different approaches with regard to administering a substance. With transdermal administration, the nature of the barrier through which the active substance

has to be transported constitutes an important and essential issue with regard to the choice of the voltage wave form. The invention is based on surprising improvements which have been achieved and are particular to transdermal administration. Shapland does not disclose a device for transdermal administration and does not disclose any transdermal administration method. Revised claim 1 highlights the important combination of features including electrodes which are skin application electrodes with one of the electrodes holding the vehicle containing the active ingredient to be transdermally administered. This represents a combination of features which is neither taught nor suggested by Shapland. Shapland clearly does not disclose the method steps of applying electrodes on the skin of the patient and does not disclose transdermally transferring the active compound as claimed.

Another important distinction between the invention and Shapland relates to the particular current which is generated and applied according to the device and method claims presented. The device claims and method claims both require the use or provision of a generator which generates a one-way current which is modulated in amplitude by a modulator of periodic nature. Shapland et al. clearly fails to teach and clearly fails to suggest this. A consideration of Figures 7A through 7F of Shapland shows that the disclosed one-way alternating currents are without modulation. This can be compared for example to the example at Figure 4 of the present application which shows the generated one-way current signal, applied between the electrodes, which is modulated in amplitude by a modulating signal of a periodic nature. In the example at Figure 4 the voltage wave form is shown for one possible embodiment. The one-way current (or voltage) is a rectified sinusoidal wave form current (or

voltage). The amplitude of the rectified sinusoidal curve is modulated by a modulator which has a saw-tooth waveform. The saw-tooth waveform of the modulator is periodic. The final resulting current (or voltage) waveform applied by the electrodes is the modulated one-way current waveform, namely a combination of the two specific waveforms, the basic one-way waveform and the periodic modulator. It is clear that the disclosure of Shapland relates to a periodic waveform with no amplitude modulation.

The two points noted above are critical in that the one-way current applied which is modulated in amplitude by a modulating signal of a periodic nature. This presents particular and significant advantages with regard to transdermally transferring the active compound. The particular choice of waveform is a not a design option. Instead, this provides a critical and important improvement over prior art transdermal applications. The claimed device and method differ from the teachings of Shapland because of the nature of such transdermal application, namely the barrier through which the drug must be administered, is quite different. This explains why two conceptionally different waveforms of the applied voltage are used.

The person of ordinary skill in the art is provided with no direction, incentive or motivation to depart from the teachings of Shapland and provide the combination of features as claimed. The person of ordinary skill in the art is not provided with any teachings that would lead to a modification of the Shapland device in such a way to have external electrodes, (skin applied electrodes) rather than the catheters as disclosed. Further, there is absolutely no suggestion or teaching of modifying the rather simple waveforms used according to the Shapland teachings to obtain a complex modulating waveform as claimed.

The person of ordinary skill in the art is presented with no teachings and no suggestions of modulating the waveform disclosed by Shapland with a periodic modulator in order to administer the drugs through a different barrier (to administer the drugs through the skin as opposed through the wall of a blood vessel as disclosed by Shapland). Accordingly, the claims as presented clearly patentably define over Shapland. Favorable reconsideration is requested. Favorable consideration of the new claims is also requested.

Claims 10 and 17 have been rejected as being anticipated by Ostrow. However, Ostrow does not disclose the device as claimed. There is no suggestion of the features specified in claims 1 and 12 (see discussion above with regard to Shapland). Ostrow does not teach and does not suggest electrodes for skin application and does not teach and does not suggest electrodes for skin applications suitable for holding a vehicle containing the active compound. A greater significance is the fact that Ostrow does not disclose a waveform as claimed and as discussed above. Accordingly, reconsideration of the rejection based on Ostrow is requested.

Further and favorable action on the merits is requested.

Respectfully submitted
for Applicant,

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